Objection to Abstract

The Action objects to the Abstract of the disclosure for allegedly not reflecting the invention as elected. Applicants have amended the Abstract to focus more specifically on the elected subject matter. Applicants submit that the Abstract accurately reflects the elected invention and, therefore, respectfully request reconsideration and withdrawal of this objection.

Rejection Under 35 U.S.C. § 101 and 35 U.S.C. § 112, First Paragraph

Claims 61-66 stand rejected under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph, on the alleged basis that the claimed invention lacks a patentable utility. The Action alleges that the claims are not supported by a substantial utility, since the specification allegedly does not support the assertion that polypeptides corresponding to SEQ ID NO:786 (L552S) may be used for cancer diagnosis or treatment. More specifically, the Action alleges that these asserted utilities are based upon the presumption that L552S polypeptides are specifically expressed in lung tumor and that the instant specification fails to provide evidence that L552S polypeptides are overexpressed in lung tumor cells.

Applicants respectfully submit that the Action has failed to establish a *prima facie* showing of lack of utility for the claimed invention under either 35 U.S.C. § 101 or 35 U.S.C. § 112, first paragraph. Applicants submit that when an applicant has asserted that a claimed invention is useful for any particular purpose and the assertion would be considered credible by a person of ordinary skill in the art, a rejection based on lack of utility should not be imposed. Utility Examination Guidelines, 66 Fed. Reg. 1099, 1098 (2001). The credibility of an assertion of utility is assessed by one of ordinary skill in the art in view of the disclosure and any other probative evidence of record. *Id.* Applicants submit that a skilled artisan would find credible the assertion that polypeptides of SEQ ID NO:786 are useful in the detection of lung cancer, based upon the disclosure that polynucleotides encoding said polypeptides are overexpressed in lung cancer. One of ordinary skill in the art would recognize that polypeptide expression levels are directly linked to mRNA expression levels, since expression of mRNA is absolutely required for protein expression. Furthermore, one of ordinary skill in the art is apprised of the fact that overexpression of an mRNA generally translates to overexpression of its encoded polypeptide.

Hence, a skilled artisan would find the assertion that the polypeptides of SEQ ID NO:786 are useful in the detection of lung cancer to be entirely credible.

Furthermore, Applicants point out that a *prima facie* showing of no specific and substantial credible utility must establish that it is more likely than not that a person skilled in the art would not consider credible any specific and substantial utility asserted by the applicant for the claimed invention. *Id.* Applicants submit that the Action has not established that it more likely than not that the skilled artisan would find Applicants' assertion that the claimed polypeptides are useful in the detection of lung cancer to lack credibility. On the contrary, Applicants submit that the skilled artisan would certainly believe it more likely than not that polypeptides of SEQ ID NO:786 are useful in the detection of lung cancer, given that the polynucleotides encoding said polypeptides are clearly overexpressed in lung cancer. Applicants also note that a statement of fact made by an applicant in relation to an asserted utility must be treated by the Examiner as true, unless countervailing evidence can be provided that shows that one of ordinary skill in the art would have a legitimate basis to doubt the credibility of such a statement. *Id.* Since one of ordinary skill in the art would find the instant assertion of utility to be entirely credible, and the Action provides no countervailing evidence indicating otherwise, the Action has not established a *prima facie* showing of lack of utility. Accordingly, Applicants respectfully submit that this rejection should be properly withdrawn.

Should the rejection be maintained, Applicants respectfully traverse the rejection and submit that the invention possesses both specific and substantial utility. Applicants submit that the L552S polypeptide sequence set forth in SEQ ID NO:786 is useful, for example, for the detection of cancer, particularly lung cancer. Furthermore, Applicants submit that one of ordinary skill in the art would readily appreciate the usefulness of L552S polypeptides for the detection of cancer, based upon the experimental results set forth in the instant specification.

Applicants submit that the specification as filed clearly shows that the polynucleotide sequence encoding SEQ ID NO:786 is overexpressed in lung tumor tissue. SEQ ID NO:786 is an amino acid sequence encoded by the polynucleotide sequence of SEQ ID NO:69, which was isolated from a lung adenocarcinoma-specific subtracted cDNA library, as described in Example 1. Subsequent mRNA expression analysis revealed that SEQ ID NO:69 was overexpressed in lung tumors as compared to all normal tissues tested (page 70, line 26 -

page 71, line 11). Based upon the expression pattern of its encoding mRNA, Applicants submit that a skilled artisan would understand that SEQ ID NO:786 would be similarly expressed in a lung tumor-associated manner. Consequently, a skilled artisan would recognize that the polypeptide sequence of SEQ ID NO:786 possesses specific and substantial utility for the detection of lung cancer.

Applicants further submit that Applicants are not required to provide evidence sufficient to establish that an asserted utility is true "beyond a reasonable doubt" or a matter of statistical certainty. M.P.E.P., 8th ed. § 2107.02, VII, *citing In re Irons*, 340 F.2d 974, 978 (CCPA 1965) and *Nelson v. Bowler*, 626 F.2d 853, 856-57 (CCPA 1980). Instead, evidence is sufficient if, considered as a whole, it leads a person of ordinary skill in the art to conclude that the asserted utility is more likely than not true. *Id.* Applicants submit that the skilled artisan would certainly find it more likely than not true that the claimed polypeptides are useful in the detection of lung cancer, since polynucleotides encoding said polypeptides are overexpressed in lung cancer. The skilled artisan would readily conclude that it is more likely than not true that a polypeptide encoded by a polynucleotide overexpressed in lung cancer is, itself, also overexpressed in lung cancer, given the well-established relationship between nucleic acid and polypeptide expression. Thus, Applicants submit that the claimed invention clearly possesses patentable utility and respectfully request that this rejection be reconsidered and withdrawn.

Rejection Under 35 U.S.C. § 102(b)

Claim 62 stands rejected under 35 U.S.C. § 102(b) as allegedly anticipated by numerous references, including the polypeptide of accession number AAW31603, which allegedly contains 21 amino acid residues of SEQ ID NO:786.

Applicants respectfully traverse this rejection and submit that the cited references do not disclose a polypeptide comprising the sequence of either SEQ ID NO:786 or a fragment comprising at least 10 amino acid residues of SEQ ID NO:786, as claimed. The polypeptide comprising the sequence of SEQ ID NO:786 and any fragment thereof comprising at least 10 amino acid resides necessarily comprise at least 10 contiguous amino acid residues of SEQ ID NO:786. The polypeptide of accession number AAW1603 does not contain 10 contiguous amino acid residues of SEQ ID NO:786 and, therefore, does not anticipate the claimed invention.

Nonetheless, solely to expedite prosecution and without acquiescing to this rejection, claim 62 has been amended to recite "a fragment thereof comprising at least 20 contiguous amino acid residues of SEQ ID NO:786." Support for the this amendment can be found, *e.g.* on page 41, lines 5-9, which describes portions of polypeptides of the invention comprising at least 20 amino acids. Applicants respectfully request that this basis of rejection be withdrawn.

* * *

Applicants wish to thank the Examiner for acknowledging the references cited in the initial IDS. However, Applicants note that the Examiner has not initialed the references cited in the Supplemental IDS or the Second Supplemental IDS. In addition, since the mailing of the instant Action, Applicants have submitted a Third Supplemental IDS. Applicants respectfully request that these references be initialed by the Examiner and their consideration made of record in the next communication. For the Examiner's convenience, we have enclosed a copy of the relevant PTO Forms 1449.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**Version With Markings to Show Changes Made.**"

Applicants respectfully submit that the claims in the application are allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,
Tongtong Wang et al.
SEED Intellectual Property Law Group PLLC

Carol D. Laherty, Ph.D.
Registration No. 51,909

CDL:sd

Enclosures:
Postcard
Copy of Forms PTO 1449

701 Fifth Avenue, Suite 6300
Seattle, Washington 98104-7092
Phone: (206) 622-4900
Fax: (206) 682-6031

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Abstract:

Please replace the original Abstract with the following rewritten Abstract:

~~Compositions and methods for the therapy and diagnosis of cancer, such as lung cancer, are disclosed. Compositions may comprise one or more lung tumor proteins, immunogenic portions thereof, or polynucleotides that encode such portions. Alternatively, a therapeutic composition may comprise an antigen presenting cell that expresses a lung tumor protein, or a T cell that is specific for cells expressing such a protein. Such compositions may be used, for example, for the prevention and treatment of diseases such as lung cancer. Diagnostic methods based on detecting a lung tumor protein, or mRNA encoding such a protein, in a sample are also provided.~~ Compositions for the therapy and diagnosis of cancer, such as lung cancer, are disclosed. Compositions may comprise cancer-associated L552S polypeptides, for example, as set forth illustratively in SEQ ID NO:786, or portions or variants thereof. Such compositions may be used, for example, in the diagnosis, prevention, and treatment of diseases such as lung cancer.

In the Claims:

Claims 62, 65, and 66 are amended to read as follows:

62. (Amended) An isolated polypeptide comprising the amino acid sequence of SEQ ID NO:786, or a fragment thereof comprising at least ~~10~~ 20 contiguous amino acid residues of SEQ ID NO:786~~, wherein said fragment binds an antibody having specificity for the polypeptide of SEQ ID NO:786~~.

65. (Amended) A composition comprising a polypeptide of any one of claims 61-~~64~~ or 62 and a physiologically acceptable carrier.

66. (Amended) A composition comprising a polypeptide of any one of claims 61-~~64~~ or 62 and a non-specific immune response enhancer.